

1K060653

001 2 4 2006

## 5. 510(k) Summary

### DermaCare, Incorporated – ThermaClear™ Device

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

<b>Owner's Name and Address:</b>	DermaCare, Inc. 6248 Preston Avenue Livermore, CA 94551 (925) 371-3900 – Telephone (925) 371-3903 – Fax
<b>Contact Information:</b>	Heidi Stark DermaCare, Inc. 6248 Preston Avenue Livermore, CA 94551 (925) 371-3900 – Telephone (925) 371-3903 – Fax
<b>Date Prepared:</b>	March 2, 2006
<b>Device Trade Name:</b>	ThermaClear™
<b>Common Name:</b>	Acne Treatment Device
<b>Classification Name:</b>	Class II - Laser instrument, surgical, powered (21 CFR 878.4810, Product Code GEX)
<b>Predicate Devices:</b>	Tyrell, Inc. Zeno K043377  Radiancy (Israel) Ltd. Radiancy Acne System With ClearTouch™ K032205

#### Description of the Device:

ThermaClear™ is a portable hand-held device that uses a short thermal pulse to treat mild to moderate inflammatory acne. The treatment tip is comprised of biocompatible

material and delivers a short duration thermal pulse that heats the area being treated. The device is powered by two AA alkaline batteries.

**Indications for Use:**

ThermaClear™ is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

**Performance Data:**

Non-clinical and clinical performance testing was conducted with the ThermaClear™ device.

**Preclinical Testing**

ThermaClear™ was tested for EMI in accordance with the IEC 60601-1 standard. ThermaClear™ operates within the EMI emission, susceptibility and static discharge levels specified in the IEC 60601-1 standard.

**Clinical Testing**

Clinical testing was conducted in both a controlled practitioner office environment and a consumer home-use environment and submitted as part of the 510(k) application to confirm that ThermaClear™ is as safe and effective as the predicate device. The controlled clinical study design was a randomized, blinded study.

**Substantial Equivalence:**

ThermaClear™ and its predicate devices are all devices that use either heat or light to treat the dermatological condition of mild to moderate acne by exposing the surface of the skin to a precise energy fluence. The delivered energy heats the skin to accelerate resolution of the acne lesion with no risk of burns. The minor differences in the technological characteristics of ThermaClear™ and its predicate devices do not raise any new issues of safety or efficacy. Thus, ThermaClear™ is substantially equivalent to the predicate device for treatment of mild to moderate acne.

**Conclusion:**

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the proposed device has been shown to be safe and effective for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DermaCare, Inc.  
% Mr. Peter Scocimara  
CEO/President  
6248 Preston Avenue  
Livermore, California 94551

OCT 24 2006

Re: K060653

Trade/Device Name: ThermaClear  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery  
and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: July 24, 2006  
Received: July 26, 2006

Dear Mr. Scocimara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

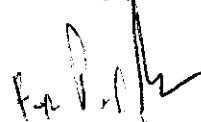
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Peter Scocimara

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4. Indications for Use Statement

510(k) Number (if known): 1K060613

Device Name: ThermaClear

Indications for Use: ThermaClear is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

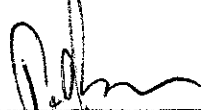
AND/OR

Over-The-Counter Use X  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

Page 1 of 1

1K060613 Page 7  
**510(k) Number** Proprietary and Confidential